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DEVICE SETUP GUIDE IN THE OPERATING ROOM

USING THE HEARTMATE TOUCH™ COMMUNICATION SYSTEM WITH THE HEARTMATE 3™ LEFT VENTRICULAR ASSIST DEVICE

HeartMate 3™ Left Ventricular Assist System (LVAS)

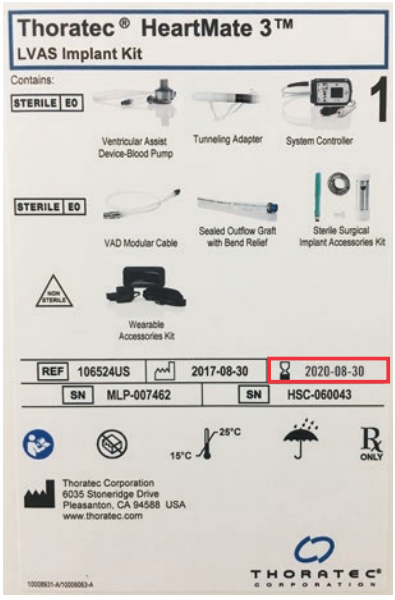
DEVICE PREPARATION SETUP GUIDE

EQUIPMENT NEEDED FOR PUMP PREP

Power Module with patient cable and wireless adapter is set up and powered on. The HeartMate Touch™ Communication System is fully charged and turned on. It should be plugged in to an outlet during the implant procedure. A backup system should be nearby.

Two fully charged 14-volt lithium-ion batteries and a pair of battery clips are readily available.

Primary and backup HeartMate 3™ LVAS implant kits are required. Verify the expiration dates are valid. If not, obtain another implant kit.



The following items will be needed from the implant kit:

- Pump and implant accessories
- System Controller
- Modular Cable with cap
- Outflow Graft with bend relief

SET UP THE TABLE FOR PUMP PREP

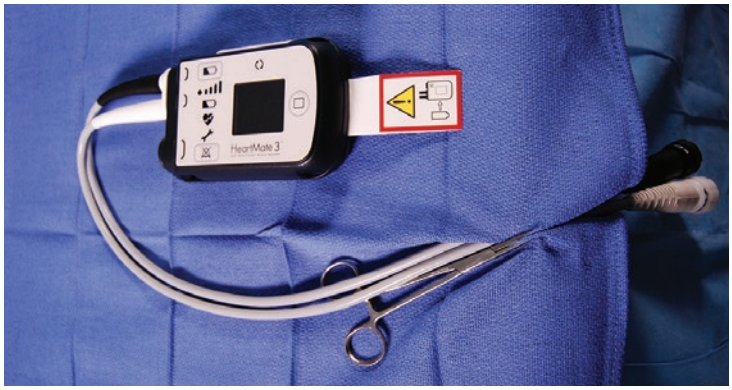
Perform pump preparation in a low traffic area of the operating room (OR) suite. Place the following items onto the sterile field:

- 1- to 1.5-liter graduated pitcher
- 2 basins — separate basin with antibiotic solution
- Bulb syringe
- 3 blue towels
- 3–4 lap sponges
- Powder-free finger cot
- Hemostat

SET UP THE SYSTEM CONTROLLER

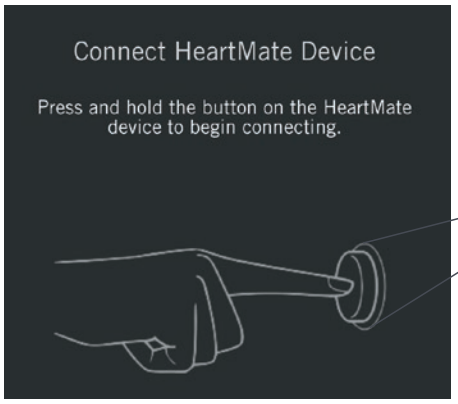
1. Open the HeartMate 3™ LVAS System Controller box, remove the emergency backup battery box (non-sterile) and set it aside. It will be inserted into the controller at the end of the case once the sterile field has been taken down.

2. Open the System Controller outer tray and pass the sterile inner tray off to a sterile person. Position the System Controller on the table with the white and black power cables draped slightly off the table. Secure them to the table drape with a hemostat to ensure most of the length of the power cables remains in the sterile field.

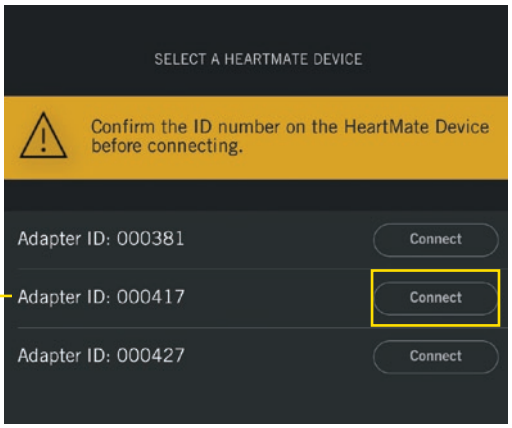


3. With the tablet turned on, tap 

to open the HeartMate Touch™ App. Then press and hold the button on the HeartMate Touch™ Wireless Adapter until a blinking blue light appears.



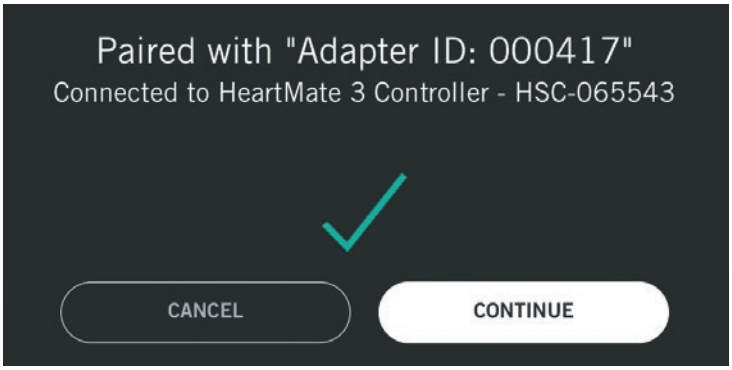
4. Select the Adapter ID number that matches the number on the HeartMate Touch™ Wireless Adapter label. Then tap **Connect.**



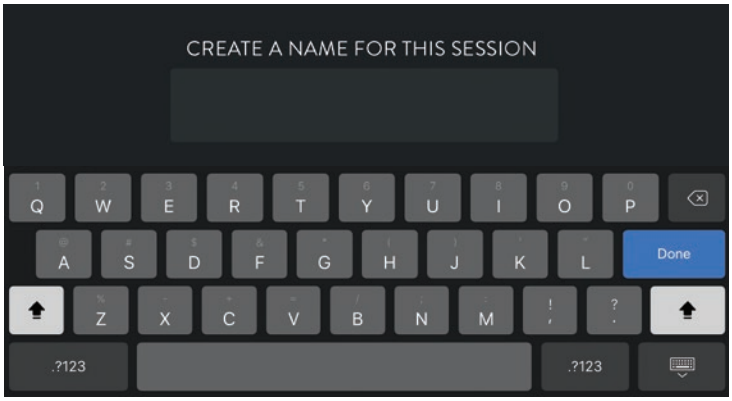
SET UP THE SYSTEM CONTROLLER (CONTINUED)

5. Next, a non-sterile individual should connect the System Controller power cable to the Power Module patient cable — white to white and black to black.

6. Tap **CONTINUE** when the button becomes active. Confirm the Adapter ID number and System Controller serial number are correct.

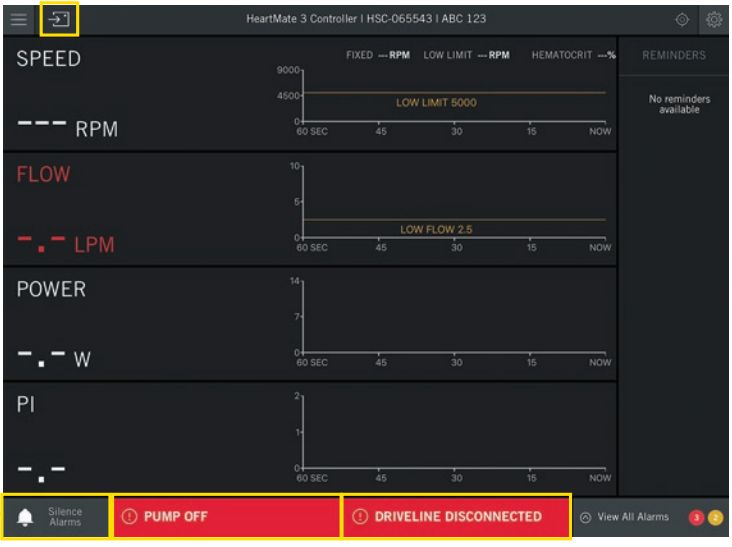


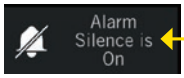
7. Create a name for the session following your center's HIPPA guidelines. Only use a–z, 0–9, underscore, period or spaces. Then tap **Done.**



8. Silence the hazard alarms by pressing the **Silence Alarms** button on the Power Module or HeartMate Touch™ App Alarm Status bar. **Do not silence the alarms using the System Controller.**

9. Verify that the **PUMP OFF** and **DRIVELINE DISCONNECTED** alarms are displayed on the Monitor view. There should also be a flashing communication icon on the navigation bar.

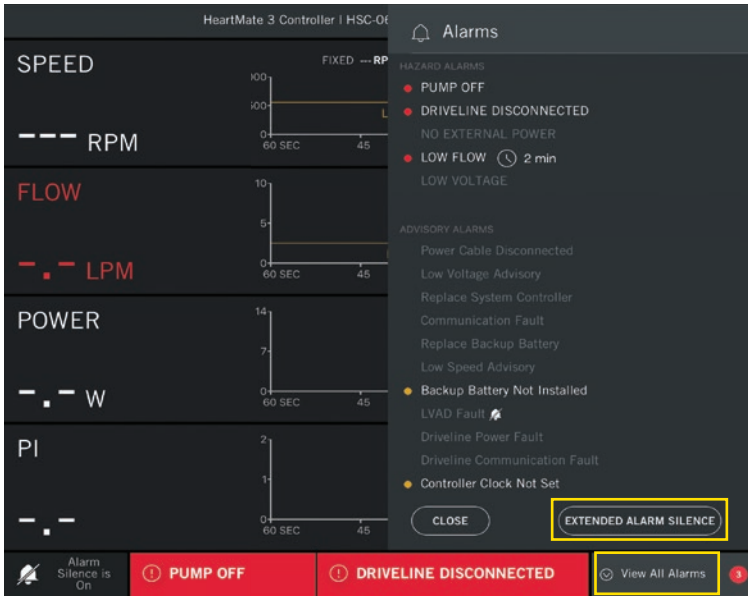




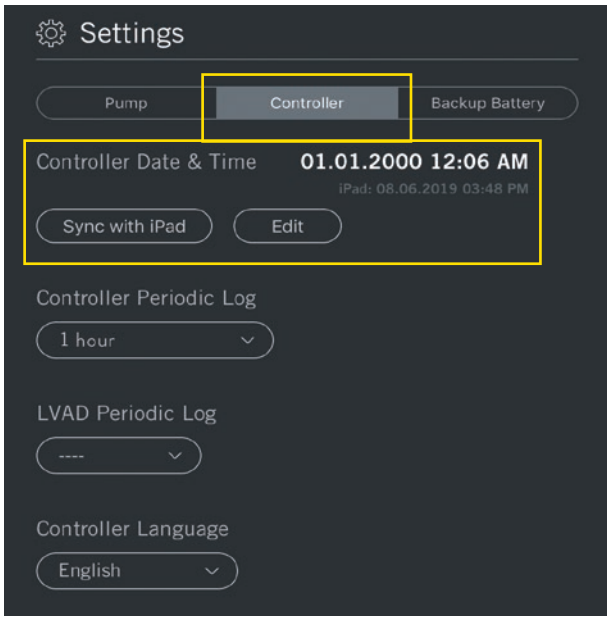
SET UP THE SYSTEM CONTROLLER (CONTINUED)

10. Tap **View All Alarms** on the Alarm Status bar and activate **EXTENDED ALARM SILENCE** to silence all alarms for 4 hours.

11. Confirm **PUMP OFF**, **DRIVELINE DISCONNECTED**, **LOW FLOW**, **Backup Battery Not Installed** and **Controller Clock Not Set** alarms are active. Then close the Alarms panel.

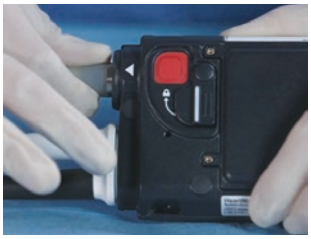


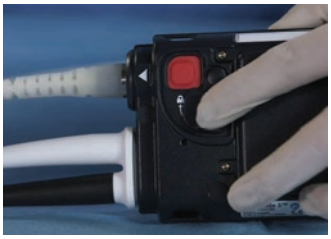
12. Access the **Controller** tab of the Settings panel to set the System Controller date and time. Then close the Settings panel.



13. Pass the Modular Cable up to the sterile field. Push the Modular Cable cap onto the end of the Modular Cable. Press firmly until the connector bottom is inside the cap. The cap protects the connector from fluids and debris.

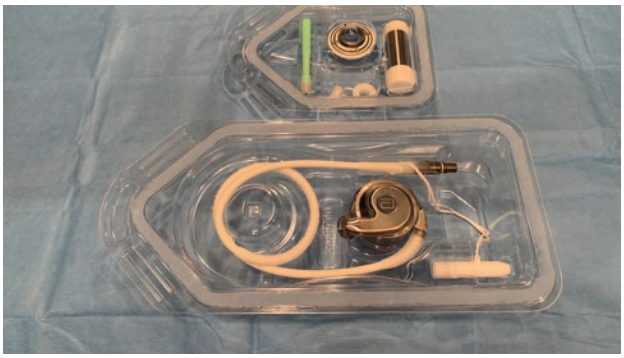
14. Connect the Modular Cable to the System Controller by matching arrow to arrow. Gently tug on the end of the connector to ensure the cable is fully engaged. Then close the safety lock on the back of the System Controller.





PREPARING THE PUMP

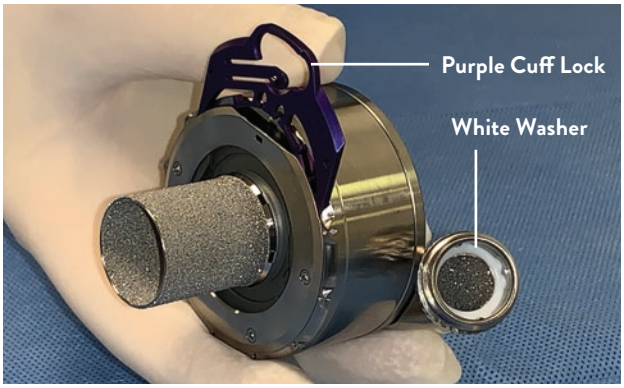
1. Inspect the graduated pitcher for any debris. Add 1 liter of injectable sterile normal saline to the pitcher; verify no debris is present after adding the saline.



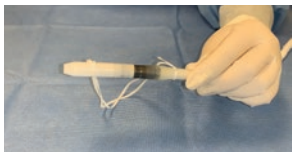
2. Open the HeartMate 3™ LVAS pump box and pass the pump and implant accessories onto the sterile field.

3. Remove the thread protector set and place it in a safe place on the table. Pass the remaining items up to the instrument table.

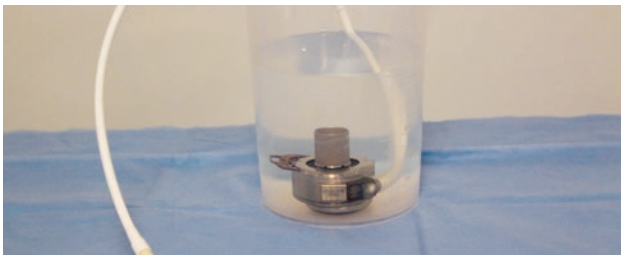
4. Remove the pump from the sterile package. Verify a white washer is present in the pump outlet and ensure the purple cuff lock is fully extended.



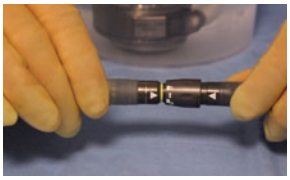
5. Screw the tunneling adapter onto the pump cable connector until the yellow line is covered.



6. Submerge the pump in the graduated pitcher of sterile normal saline, ensuring that the pump is fully submerged and free of air and debris. The inlet cannula should be pointing up. Gently shake the pump to remove any entrapped air. Dry your gloves.



7. Remove the tunneling adapter and Modular Cable cap. Connect the two cables by aligning the triangles, applying firm force to engage the cables and rotating the locking nut until the clicking sound stops and the yellow line is no longer visible. Keep the connection dry.

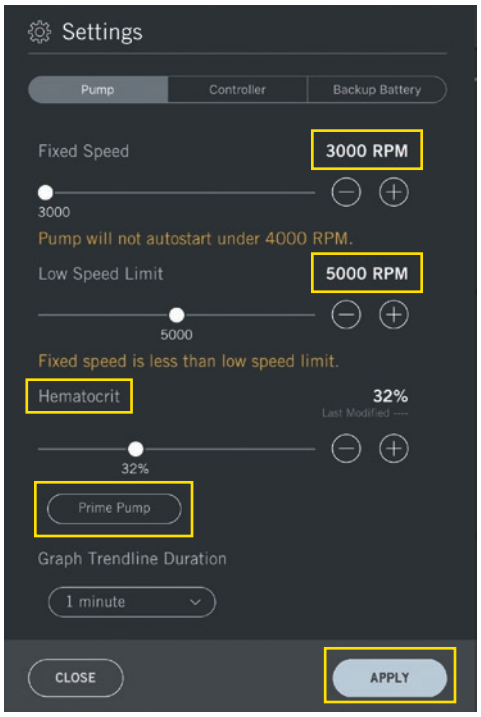


PREPARING THE PUMP (CONTINUED)

8. Access the Clinical view, and verify the **DRIVELINE DISCONNECTED** alarm has cleared, the **LOW FLOW** alarm displays, the Pump **FLOW** displays 0.0 and the Pump **POWER** displays 0.7–1 watt as the rotor levitates.

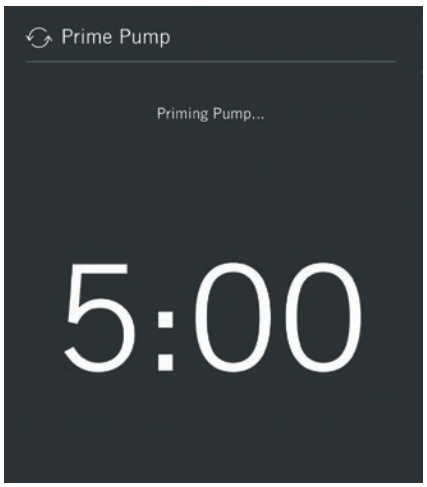
9. Access the **Pump** tab of the Settings panel and verify the fixed speed is set at 3,000 rpm and the low speed limit at 5,000 rpm. If not, enter the correct speed value, then tap **APPLY** if any change is made.

   Enter the patient's hematocrit value, then tap **APPLY.** It can only be entered when the pump is connected to the controller. It is used to increase the accuracy of the flow estimator. Tap **Prime Pump** and **CONTINUE**.



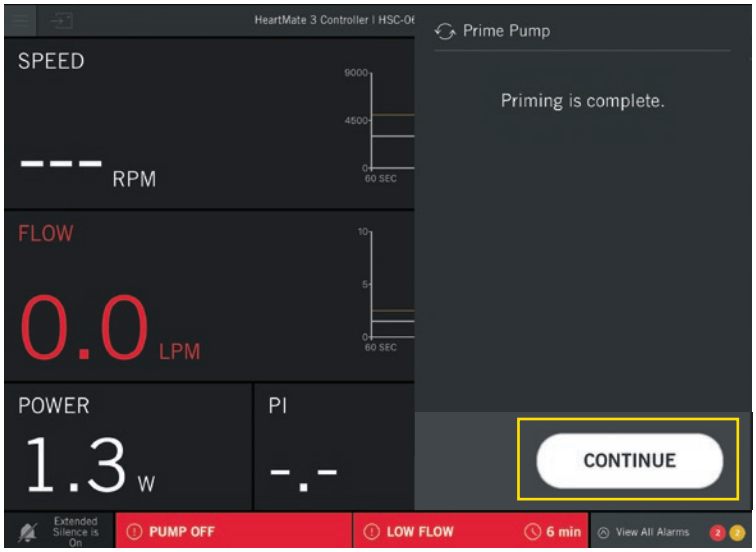
10. The pump will start and a 5-minute timer will count down.

    Do NOT allow air or debris to enter the pump, and NEVER run the pump dry. If the pump has been dropped or run dry, do not use it. Obtain another pump.



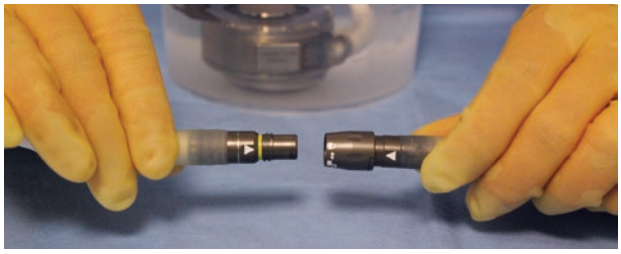
PREPARING THE PUMP (CONTINUED)

11. Once pump priming is complete, the pump will automatically stop. Confirm the pump has stopped. Press **CONTINUE** to close the Prime Pump tab.

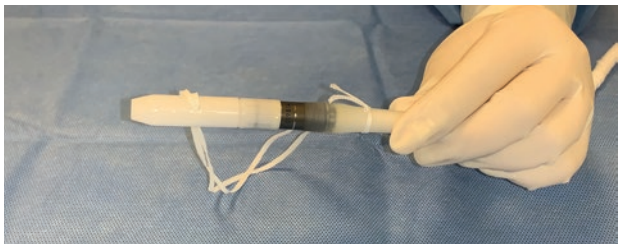


12. Perform the following steps to disconnect the pump from the controller:

a. Disconnect the pump cable from the Modular Cable.

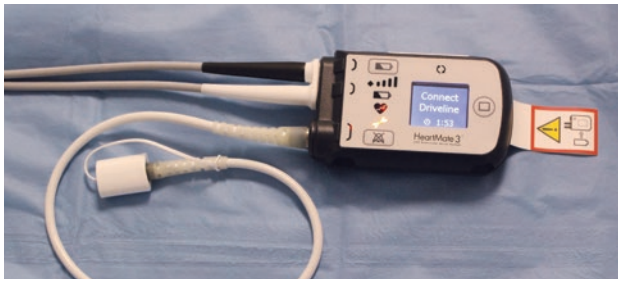


b. Attach the tunneling adapter to the pump cable connector.



c. Place the Modular Connector Cap onto the Modular Cable.

13. Secure the System Controller and attached Modular Cable so both maintain sterility — leave the controller connected to the Power Module patient cable.



ASSEMBLING THE PUMP

1. Remove the pump from the graduated pitcher. Place the thread protector on the pump outlet and open the luer-lock cap.

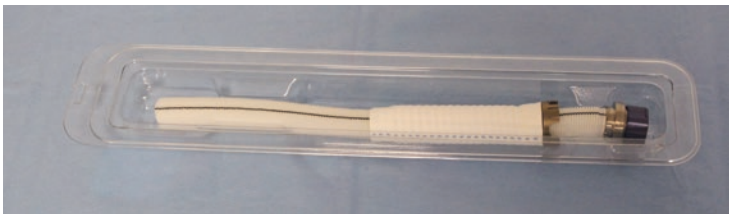
2. Using a bulb syringe, fill the pump with sterile normal saline and vent air via the luer-lock cap.

3. Close the luer-lock cap once the air bubbles have cleared. Add additional saline to fill the inlet, then cover the pump inlet cannula with a powder-free sterile glove tip or finger cot.

4. Wrap the pump and velour portion of the pump cable in antibiotic-soaked laps. Massage the solution into the velour part of the cable. Do not place the distal end of the pump cable in the solution. Place it in a sterile basin and cover with a sterile towel. Keep the pump cable end dry.

PREPARING THE OUTFLOW GRAFT

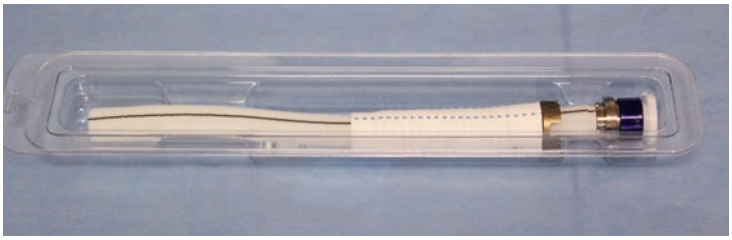
1. Open the sealed Outflow Graft foil pouch and outer tray. Pass the inner sterile tray onto the sterile field.



2. Remove the bend relief and inspect the exterior and interior of the graft. If debris is present on the interior of the graft, remove it. Then attach the open-ended thread protector onto the screw ring.

> ***Note:*** *The graft does not need to be rinsed prior to use. If it is, it must remain wet to prevent the sealant from drying out.*

3. Slide the bend relief over the sealed Outflow Graft with the metal end toward the screw ring. Place the graft into its original container and pass it up to the main table.



PRIOR TO LEAVING THE OR

1. Once the sterile field has been taken down, with the patient still connected to the HeartMate Touch™ App, install the backup battery inside the System Controller:

   a. Use the lever to remove the screw cover of the battery compartment and the screwdriver to loosen all four screws (they are threaded in and will not fall out).

   b. Remove the battery from the box. **Do not remove the rubber protection around the battery.**

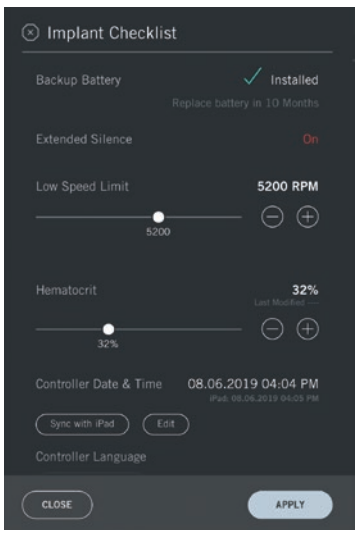
   c. Align the arrow on the battery with the arrow on the ribbon cable and insert it into the battery socket. Confirm the ribbon is secure.

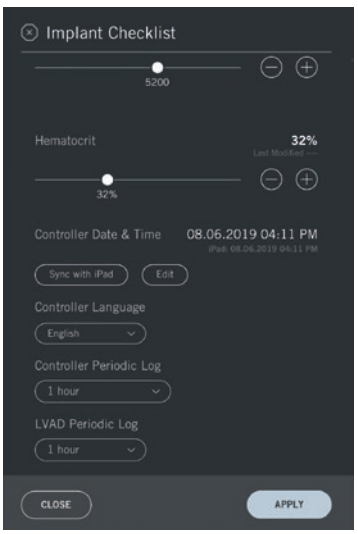
   > ***Note:*** *A green, yellow or red light may appear on the battery.*

   d. Lay the battery flat in the compartment and replace the battery cover and screw cover.

   e. Confirm the Backup Battery Not Installed alarm clears from the controller.

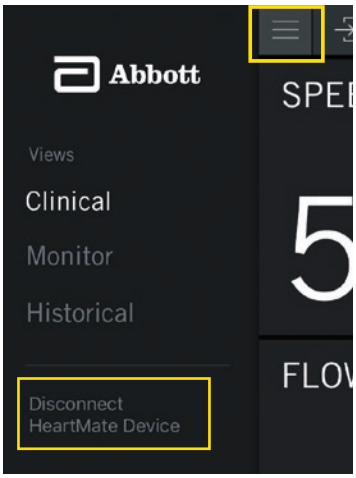
2. Review and complete the **Implant Checklist.** Inactivate the **Extended Silence** alarms by pressing the Silence Alarm button on the System Controller. If adjustments are made, tap **APPLY** after each change.

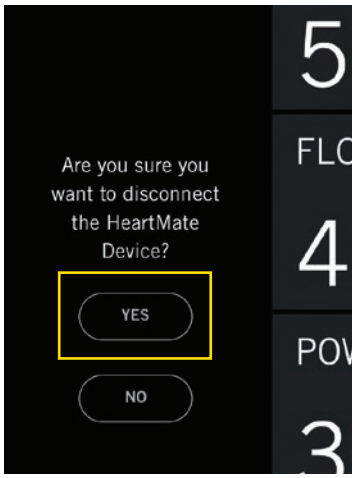




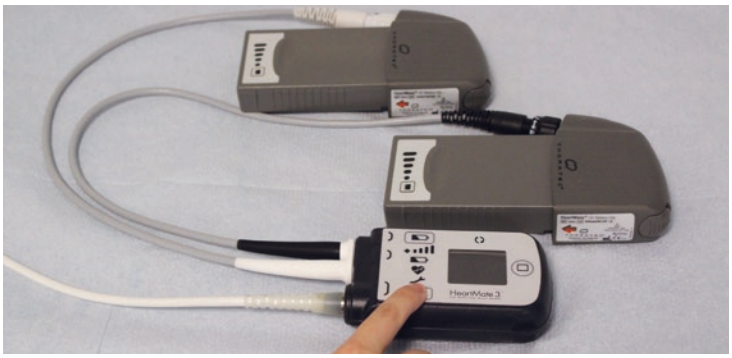
PRIOR TO LEAVING THE OR (CONTINUED)

3. From the Menu panel, tap **Disconnect HeartMate Device** and then **YES** to end the session.





4. Place the patient onto 14-volt lithium-ion batteries for transfer to the intensive care unit.

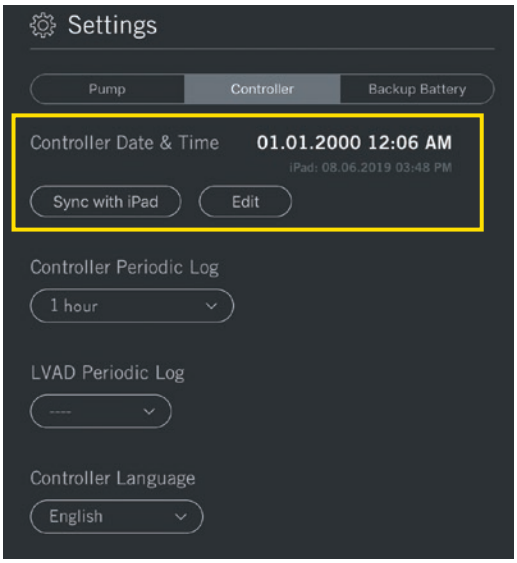


5. Perform the following steps to set up the backup System Controller:

   a. Insert the backup battery into the controller.

   b. Establish the Bluetooth® wireless connection with the HeartMate Touch™ App, then connect the controller to the Power Module.

   c. Use the **Controller** tab of the Settings panel to set the date and time, and if needed, change the controller language.



PRIOR TO LEAVING THE OR (CONTINUED)

d. Fully charge the backup battery using the Power Module or a pair of 14-volt lithium-ion batteries.

HeartMate Touch™ Communication System Overview: The HeartMate Touch™ Communication System is intended for use by clinicians in the hospital to wirelessly monitor a patient's HeartMate II™ Left Ventricular Assist System or HeartMate 3™ Left Ventricular Assist System. The HeartMate Touch Communication System is required during implant procedures and any time close monitoring of system operation is needed. It provides clinicians with the ability to program system parameters such as pump speed, assess and track alarm conditions, and view and save performance data.

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Rx Only
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications: The HeartMate 3™ Left Ventricular Assist System is indicated for providing short- and long-term mechanical circulatory support (e.g. as bridge to transplantation or myocardial recovery, or destination therapy) in patients with advanced refractory left ventricular heart failure.

Contraindications: The HeartMate 3 Left Ventricular Assist System is contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy.

Adverse Events: Adverse events that may be associated with the use of the HeartMate 3 Left Ventricular Assist System are listed here: death, bleeding, cardiac arrhythmia, localized infection, right heart failure, respiratory failure, device malfunctions, driveline infection, renal dysfunction, sepsis, stroke, other neurological event (not stroke-related), hepatic dysfunction, psychiatric episode, venous thromboembolism, hypertension, arterial non-central nervous system (CNS) thromboembolism, pericardial fluid collection, pump pocket or pseudo pocket infection, myocardial infarction, wound dehiscence, hemolysis (not associated with suspected device thrombosis) and possible pump thrombosis.

MAT-1901484 v1.0 | Item approved for U.S use only.

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